

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No. : 09/724,691 Confirmation No.: 7842  
Applicant : RANDY J. KESTEN ET AL.  
Title : INTRA-AORTIC RENAL DRUG DELIVERY CATHETER  
Filed : 11/28/2000  
TC/A.U. : 3763  
Examiner : MAIORINO, ROZ  
Docket No. : 1292-01 (FLO5360.03A)  
Cust. No. : 8156

**MAIL STOP ISSUE FEE**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22213-1450**

**INFORMATION DISCLOSURE STATEMENT  
AFTER NOTICE OF ALLOWANCE AND ISSUE FEE DUE**

Applicants submit herewith patents, publications or other information of which they are aware, for placement in the file wrapper for the above-identified application.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR 1.56(g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner.

**FORM PTO/SB/08A-PTO/SB/08B IS BEING SUBMITTED HEREWITH IN  
FIVE (5) PAGES ALONG WITH COPIES OF THE LISTED CITATIONS.**

Date: 9/21/04

Respectfully submitted,

John P. O'Banion, Reg. No. 33,201  
O'BANION & RITCHEY LLP  
400 Capitol Mall, Suite 1550  
Sacramento, CA 95814  
(916) 498-1010

**CERTIFICATION UNDER 37 CFR 1.10**

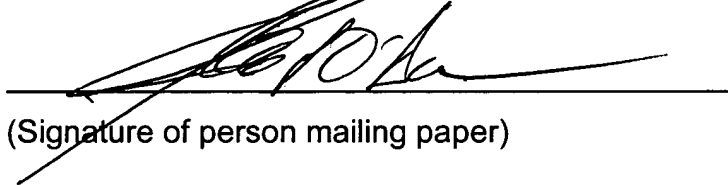
I hereby certify that the foregoing:

Information Disclosure Statement by Applicant

is being deposited with the United States Postal Service on 9/21/04 in  
an envelope as "Express Mail Post Office to Addressee" Mailing Label Number  
EV352301724US addressed to the: Commissioner for Patents, P.O. Box 1450,  
Alexandria, VA 22313-1450.

JOHN P. O'BANION

(Type or print name of person mailing paper)



(Signature of person mailing paper)

**Complete if Known**

*(use as many sheets as necessary)*

1

5

Application Number	09/724,691
Filing Date	11/28/2000
First Named Inventor	Randy J. Kesten
Art Unit	3763
Examiner Name	Roz Maiorino
Attorney Docket Number	1292-01 (FLO5360.03A)

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		US- 1,696,018		12/18/1928	Schellberg	
		US- 4,909,252		03/20/1990	Goldberger	
		US- 5,167,628		12/01/1992	Boyles	
		US- 5,226,888		07/13/1993	Arney	
		US- 5,257,974		11/02/1993	Cox	
		US- 5,345,927		09/13/1994	Bonutti	
		US- 5,370,617		12/06/1995	Sahota	
		US- 5,421,826		06/06/1995	Crocker, et al.	
		US- 5,476,453		12/19/1995	Mehta	
		US- 5,599,306		02/04/1997	Klein, et al.	
		US- 5,613,949		03/25/1997	Miraki	
		US- 5,713,860		02/03/1998	Kaplan, et al.	
		US- 5,720,735		02/24/1998	Dorros	
		US- 5,766,151		06/16/1998	Valley, et al.	
		US- 5,807,895		09/15/1998	Stratton, et al.	
		US- 5,928,132		07/27/1999	Leschinsky	
		US- 5,968,013		10/19/1999	Smith, et al.	
		US- 6,068,629		05/30/2000	Haissaguerre, et al.	
		US- 6,287,608		09/11/2001	Levin, et al.	
		US- 6,508,787		01/21/2003	Erbel, et al.	

[illegible]Date  
Considered

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*



Sheet	2	of	5
-------	---	----	---

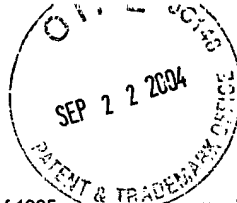
Application Number	09/724,691
Filing Date	11/28/2000
First Named Inventor	Randy J. Kesten
Art Unit	3763
Examiner Name	Roz Maiorino
Attorney Docket Number	1292-01 (FLO5360.03A)

[illegible][illegible]

Date	
Considered	

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/724,691
				Filing Date	11/28/2000
				First Named Inventor	KESTEN, ET AL.
				Art Unit	3763
				Examiner Name	Roz Maiorino
Sheet	3	of	5	Attorney Docket Number	1292-01 (FLO5360.03A)

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		LASS, et al., Cardiovascular and Renal Hemodynamic Effects of Intravenous Infusions of the Selective DA1 Agonist etc., Circulation 1988;78:1310-1315	
		VARI, et al., Induction, Prevention and Mechanisms of Contrast Media-Induced Acute Renal Failure, Kidney International, 1988; 33:669-707	
		PARFREY, et al., Contrast Material-Induced Renal Failure in Patients with Diabetes Mellitus, Renal Insufficiency, or Both, N Engl J Med 1989; 320:143-149	
		SCHWAB, et al., Contrast Nephrotoxicity: A Randomized Controlled Trial of a Nonionic and an Ionic Radiographic Contrast Agent, N Engl J Med, 1989, 320:149-153	
		MARGULIES, et al., Induction and Prevention of Radiocontrast-Induced Nephropathy in Dogs with Heart Failure, Kidney Int. 1990; Vol. 38:1101-1108	
		PATEL, et al., Intravenous Fenoldopam Infusion in Severe Heart Failure, Cardiovasc Drugs Ther 1993;7:97-101	
		SHUSTERMAN, et al., Fenoldopam, But Not Nitroprusside, Improves Renal Function etc. Am J of Medicine, 95:161-168 (1993)	
		SOLOMON, et al., Effects of Saline, Mannitol, and Furosemide on Accute Decreases in Renal Function etc., N Engl J Med 1994; Vol 331 No. 21 pp. 1416-1420	
		STRICK, et al., Direct Measurement of Renal Medullary Blood Flow in the Dog, Am J. Physiol. 267 (Regulatory Integrative Comp. Physiol. 36): R253-R2259, 1994	
		RUDNICK, et al., Nephrotoxicity of Ionic and Noionic Contrast Media in 1196 Patients: A Randomized Trial, Kidney International, 1995;47:254-261	

Examiner Signature	Date Considered
-----------------------	--------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

SEP 22 2004

PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Sheet	4	of	5	Application Number	09/724,691
				Filing Date	11/28/2000
				First Named Inventor	KESTEN, ET AL.
				Art Unit	3763
				Examiner Name	Roz Maiorino
				Attorney Docket Number	1292-01 (FLO5360.03A)

## **NON PATENT LITERATURE DOCUMENTS**

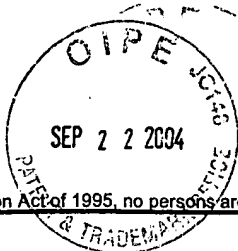
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		MARGULIES, et al., Intra-Arterial Atrial Natriuretic Factor (ANF) Attenuates Radiocontrast-Induced etc., Renal Pathology, unknown date, pp. 666, Abstract only	
		DEL GRECO, The Kidney in Congestive Heart Failure, Modern Concepts of Cardiovascular Disease, Sept. 1975, Vol 44, No. 9, pp. 47-52	
		EISENBERG, et al., Renal Failure After Major Angiography, Am J Med, Jan. 1980, Vol. 68, pp. 43-46	
		EISENBERG, et al., Renal Failure after Major Angiography Can be Avoided with Hydration, AJR, May 1981; 136:859-861	
		THOMAS, et al., Influence of Bradykinin and Papaverine on Renal etc., Renal Physiology, Basel 5:197-205 (1982)	
		D'ELIA, et al., Nephrotoxicity from Angiographic Contrast Material, "A prospective Study," Am J Med, May 1982, Vol. 72, pp. 719-725	
		THOMAS, et al., Glomerular Filtration Dynamics During Renal Vasodilation etc. Am. J. Physiol. 244:F606-F611 (1983)	
		ELKAYAM, et al., Renal Hemodynamic Effects of Vasodilation with Nifedipine and Hydralazine in Patients With Heart Failure, JACC Dec 1984;Vol 4, No. 6, pp. 1261-1267	
		MASON, et al., Renal Dysfunction After Arteriography, JAMA, 1985;253:1001-1004	
		TALIERCIO, et al., Risks for Renal Dysfunction with Cardiac Angiography, Annals of Internal Medicine, 1986;104:501-504	

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	09/724,691
Filing Date	11/28/2000
First Named Inventor	KESTEN, ET AL.
Art Unit	3763
Examiner Name	Roz Maiorino
Attorney Docket Number	1292-01 (FLO5360.03A)

Sheet 5 of 5

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		ELKAYAM, et al., Renal Vasodilatory Effect of Endothelial Stimulation in Patients with Chronic Congestive Heart Failure, J Am Coll Cardiol 1996;28:176-182	
		MCCARTHY, Animal Models in Medical Device Development and Qualification, Charles River Laboratories, Vol 10(2) 1997	
		MCCULLOUGH, et al., Acute Renal Failure after Coronary Intervention: Incidence, Risk Factors, and Relationship to Mortality, Am J Med. 1997;103:368-375	
		DRESCHER, et al., Prevention of Contrast Medium-Induced Renal Vasospasm by Phosphodiesterase Inhibition, Invest Radiol 1998;33:858-862	
		BAKRIS, et al., Renal Hemodynamics in Radiocontrast Medium-Induced Renal Dysfunction etc. Kidney International, Vol. 56 pp. 206-210 (1999)	
		KIM, et al., Fluoroscopic Landmarks for Optimal Visualization of the Proximal Renal Arteries, JVIR, 10:37-39 (1999)	
		HEYMAN, et al., Pathophysiology of Radiocontrast Nephropathy, A Role for Medullary Hypoxia, Invest Radiol, 1999;34:685-691	
		STEVENS, et al., A Prospective Randomized Trial of Prevention Measures in Patients at High Risk for Contrast Nephropathy, J Am Coll Cardiol, 1999;33:403-411	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

**CERTIFICATION UNDER 37 CFR 1.10**

I hereby certify that the foregoing:

Cited References (30)

is being deposited with the United States Postal Service on 9/21/04 in  
an envelope as "Express Mail Post Office to Addressee" Mailing Label Number  
EV352301724US addressed to the: Commissioner for Patents, P.O. Box 1450,  
Alexandria, VA 22313-1450.

JOHN P. O'BANION

(Type or print name of person mailing paper)

  
(Signature of person mailing paper)